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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,843	04/24/2001	Raghbir S. Bhullar	RDID 0034US	5691

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EXAMINER
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OLSEN, KAJ K

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 09/25/2003

3

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/840,843	BHULLAR ET AL.
	Examiner Kaj Olsen	Art Unit 1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
  - 4a) Of the above claim(s) 21-24 is/are withdrawn from consideration.
- 5) Claim(s) 15-18 is/are allowed.
- 6) Claim(s) 1-14, 19, 20 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-20, drawn to a biosensor, classified in class 204, subclass 403.01.
  - II. Claims 21-24, drawn to method of making biosensor, classified in class 204 subclass 157.41.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made with screen-printed electrodes.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Jill Woodburn on 9-2-2003 a provisional election was made with traverse to prosecute the invention of group I, claims 1-20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 21-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 5, 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. In claims 5, 19 and 20, there is no antecedent basis for the terms "electrode arrays" or "electrode array".

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-5, 10, 11, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Pfab et al (USP 5,018,527).

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11. With respect to claim 1, Pfab discloses an electrochemical biosensor that comprises electrodes (23 or 100) positioned on an electrode support substrate (elements 19-21 or the upper layer portion of 103 in figures 3 and 15 respectively). Pfab further discloses electrically conductive tracks (26 or 102) positioned on a sensor support substrate (18 or the lower layer portion of 103 in figures 3 and 15 respectively), where each track is in electrical communication with one of the electrodes.
12. With respect to claim 2, figure 4 shows an embodiment of the sensor support 18 where a portion of the support is shown removed to accommodate each of the electrical elements 23. That removed portion would read on "notches" giving the claim language its broadest reasonable interpretation.
13. With respect to claims 3 and 4, the plurality of electrodes could be utilized to form electrode arrays.
14. With respect to claim 5, element 36 and 37 define an opening for one electrode array (fig. 8).
15. With respect to claim 10, elements 25 of fig. 3 are openings in alignment with a portion of the electrodes.
16. With respect to claim 11, element 95 of fig. 15 would constitute a cover substrate coupled to the sensor support substrate.
17. With respect to claim 13, fig. 4 shows the sensor support 18 and the electrode support 19 cooperating to define a channel that the electrodes 23 reside within.
18. With respect to claim 14, elements 25 of fig. 3 are openings in alignment with the channel.

19. Claims 1, 4, 5 and 10-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Sugihara et al (USP 6,132,683).
20. With respect to claim 1, Sugihara discloses a biosensor comprising electrodes 11 positioned on an electrode support 2 (fig. 2-4). Sugihara further discloses a sensor support 3 coupled to the electrode support 2 with electrically conductive tracks 9 positioned on the sensor support (fig. 2), where each of the conductive tracks is in electrically communication with one of the electrodes (col. 8, lines 51-65).
21. With respect to claims 4, 5 and 10, see claim 5 and fig. 2 showing an opening in the sensor support.
22. With respect to claim 11, element 5 of fig. 2 would constitute a cover coupled to the sensor support giving the claim language its broadest reasonable interpretation.
23. With respect to claims 12-14, the combination of the openings in cover 5 and sensor support 3, in conjunction with element 6 of the electrode support 2 would constitute the defined channel of the claims giving the claim language its broadest reasonable interpretation.

***Claim Rejections - 35 USC § 103***

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
25. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

26. Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfab in view of Yamamoto et al (USP 6,071,392).

Pfab sets forth all the limitations of the claims, but does not explicitly recite the use of a plurality of layers for the conductive tracks or did not explicitly set forth the use of carbon and silver inks. Yamamoto teaches in an alternate biosensor that a combination of layers for the conductive tracks is conventional in the art. In particular, a layer of silver is utilized because it provides high electrical conductivity whereas a layer of carbon is placed over the silver to assist in the avoidance of corrosion (paragraph bridging col. 1 and 2). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Yamamoto for the conductive tracks of Pfab in order to provide a conductive track that provides high conductivity with high resistance to corrosion. With respect to the use of gold electrodes, see Pfab, col. 9, lines 28-34. With respect to the use of "inks", the determination of patentability for the claim is based on the product itself. Because the product of the claim is identical to the invention of Pfab in view of Yamamoto, the process from which it was made is the same as or obvious over the process utilized by Pfab in view of Yamamoto (see *In re Thorpe*, 777 F.2d 695, 698).

***Allowable Subject Matter***

27. Claims 15-18 are allowed.
28. Claims 19 and 20 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.
29. The following is a statement of reasons for the indication of allowable subject matter:  
The prior art does not disclose nor render obvious a biosensor comprising all the limitations of claim 15 with particular attention to the electrically conductive tracks extending across one of the notches into engagement with one lead.

***Conclusion***

30. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chow, Patko, Shimomura, and Ward show alternate biosensors having electrically conductive tracks on supports separate from an electrode support substrate.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (703) 305-0506. The examiner can normally be reached on Monday through Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Nam Nguyen, can be reached at (703) 308-3322.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing

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of your papers. The fax number for regular communications is (703) 305-3599 and the fax number for after-final communications is (703) 305-5408.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.



Kaj K. Olsen  
Patent Examiner  
AU 1753  
September 15, 2003